

not subject to the requirements of paragraph (a) of this section if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term “fresh” used to describe pasteurized whole milk is not subject to paragraph (a) of this section because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term “fresh” to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to paragraph (a) of this section because the term implies that the food is not processed or preserved. Uses of fresh not subject to this regulation will be governed by the provisions of 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(a) The term “fresh,” when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.

(b) The terms “fresh frozen” and “frozen fresh,” when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). Blanching of the food before freezing will not preclude use of the term “fresh frozen” to describe the food. “Quickly frozen” means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(c) *Provisions and restrictions.* (1) The following do not preclude the food from use of the term “fresh:”

(i) The addition of approved waxes or coatings;

(ii) The post-harvest use of approved pesticides;

(iii) The application of a mild chlorine wash or mild acid wash on produce; or

(iv) The treatment of raw foods with ionizing radiation not to exceed the

maximum dose of 1 kiloGray in accordance with §179.26 of this chapter.

(2) A food meeting the definition in paragraph (a) of this section that is refrigerated is not precluded from use of “fresh” as provided by this section.

[58 FR 2426, Jan. 6, 1993]

Subpart G—Exemptions From Food Labeling Requirements

§ 101.100 Food; exemptions from labeling.

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either:

(i) The labeling of the bulk container plainly in view, provided ingredient information appears prominently and conspicuously in lettering of not less than one-fourth of an inch in height; or

(ii) A counter card, sign, or other appropriate device bearing prominently and conspicuously, but in no case with lettering of less than one-fourth of an inch in height, the information required to be stated on the label pursuant to section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

(3) Incidental additives that are present in a food at insignificant levels

and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(4) For the purposes of paragraph (a)(3) of this section, any sulfiting agent (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) that has been added to any food or to any ingredient in any food and that has no technical effect in that food will be considered to be present in an insignificant amount only if no detectable amount of the agent is present in the finished food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. Compliance with this paragraph will be determined using sections 20.123–20.125, “Total Sulfurous Acid,” in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 14th Ed. (1984), which is incorporated by reference and

the refinements of the “Total Sulfurous Acid” procedure in the “Monier-Williams Procedure (with Modifications) for Sulfites in Foods,” which is appendix A to part 101. A copy of sections 20.123–20.125 of the Official Methods of Analysis of the Association of Official Analytical Chemists” is available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e)(1) of the act (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g)(2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i)(1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) An open container (a container of rigid or semirigid construction, which

is not closed by lid, wrapper, or otherwise other than by an uncolored transparent wrapper which does not obscure the contents) of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than 1 dry quart, shall be exempt from the labeling requirements of sections 403(e), (g)(2) (with respect to the name of the food specified in the definition and standard), and (i)(1) of the act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will ensure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any offi-

cer or employee of the Department who requests them.

(3) The article is an egg product subject to a standard of identity promulgated in part 160 of this chapter, is to be shipped under the conditions specified in paragraph (d) (1) or (2) of this section and for the purpose of pasteurization or other treatment as required in such standard, and each container of such egg product bears a conspicuous tag or label reading "Caution—This egg product has not been pasteurized or otherwise treated to destroy viable *Salmonella* microorganisms". In addition to safe and suitable bactericidal processes designed specifically for *Salmonella* destruction in egg products, the term "other treatment" in the first sentence of this paragraph shall include use in acidic dressings in the processing of which the pH is not above 4.1 and the acidity of the aqueous phase, expressed as acetic acid, is not less than 1.4 percent, subject also to the conditions that:

(i) The agreement required in paragraph (d)(2) of this section shall also state that the operator agrees to utilize such unpasteurized egg products in the processing of acidic dressings according to the specifications for pH and acidity set forth in this paragraph, agrees not to deliver the acidic dressing to a user until at least 72 hours after such egg product is incorporated in such acidic dressing, and agrees to maintain for inspection adequate records covering such processing for 2 years after such processing.

(ii) In addition to the caution statement referred to above, the container of such egg product shall also bear the statement "Unpasteurized _____ for use in acidic dressings only", the blank being filled in with the applicable name of the eggs or egg product.

(e) Conditions affecting expiration of exemptions:

(1) An exemption of a shipment or other delivery of a food under paragraph (d) (1) or (3) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within

the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d) (2) or (3) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food constituting such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(ii) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word “processed” as used in this paragraph shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35 °F for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (d) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following paragraphs, and in such case the provisions of paragraph (e) of this section shall also apply:

(1) In the case of varieties of cheese for which definitions and standards of identity require a period of aging whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the

statement “Uncured _____ cheese for completion of curing and proper labeling”, the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, “To be cured and labeled as ‘swiss cheese,’ but if eyes do not form, to be labeled as ‘swiss cheese for manufacturing’”.

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, “_____ cheese made from unpasteurized milk. For completion of curing and proper labeling”, the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading “_____ cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as _____ cheese for manufacturing”, the blank being filled in with the applicable name of the variety of cheese.

(g) The label declaration of a harmless marker used to identify a particular manufacturer’s product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

(h) Wrapped fish fillets of nonuniform weight intended to be unpacked and marked with the correct weight at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing and marking:

(1) *Provided*, That (i) The outside container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before time of sale" and a correct statement setting forth the weight of the wrapper;

(2) *Provided further*, That it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare—ounce", the blank being filled in with the correct average weight of the wrapper used.

(3) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

(i) Wrapped clusters (consumer units) of bananas of nonuniform weight intended to be unpacked from a master carton or container and weighed at or

before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing:

(1) *Provided*, That (i) The master carton or container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before the time of sale" and a correct statement setting forth the weight of the wrapper; using such term as "wrapper tare __ ounce", the blank being filled in with the correct average weight of the wrapper used;

(2) *Provided further*, That it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(3) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton bears the required information.

[42 FR 14308, Mar. 15, 1977, as amended at 51 FR 25017, July 9, 1986; 58 FR 2188, 2876, Jan. 6, 1993; 66 FR 17358, Mar. 30, 2001]

§ 101.105 Declaration of net quantity of contents when exempt.

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. If there is a firmly established general

consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Commissioner determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, he will by regulation designate the appropriate term or terms to be used for such commodity.

(b)(1) Statements of weight shall be in terms of avoirdupois pound and ounce.

(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall:

(i) In the case of frozen food that is sold and consumed in a frozen state, express the volume at the frozen temperature.

(ii) In the case of refrigerated food that is sold in the refrigerated state, express the volume at 40 °F (4 °C).

(iii) In the case of other foods, express the volume at 68 °F (20 °C).

(3) Statements of dry measure shall be in terms of the U.S. bushel of 2,150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

(c) When the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information.

(d) The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an

ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(e) The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.

(f) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter “N” of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as “jumbo quart” and “full gallon”) that tends to exaggerate the amount of the food in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part.

(g) The declaration shall accurately reveal the quantity of food in the package exclusive of wrappers and other material packed therewith: *Provided*, That in the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration.

(h) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of

net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width (of the letter) shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide).

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(i) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than ½ inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (h)(1) through (4) of this section shall be increased by one-sixteenth of an inch.

(j) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by

weight or by liquid measure and, if applicable (1 pound or 1 pint or more) followed in parentheses by a declaration in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (see examples set forth in paragraphs (m) (1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see examples in paragraphs (m) (3) and (4) of this section).

(2) If the net quantity of contents declaration appears on a random package, that is a package which is one of a lot, shipment, or delivery of packages of the same consumer commodity with varying weights and with no fixed weight pattern, it may, when the net weight exceeds 1 pound, be expressed in terms of pounds and decimal fractions of the pound carried out to not more than two decimal places. When the net weight does not exceed 1 pound, the declaration on the random package may be in decimal fractions of the pound in lieu of ounces (see example in paragraph (m)(5) of this section).

(3) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz" or "6 oz Net wt." and "6 fl oz" or "Net contents 6 fl oz".

(k) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of fluid measure, it shall be expressed in the largest whole unit (gallons followed by common or decimal fraction of a gallon or by the next smaller whole unit or units (quarts, or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (see paragraph (m)(6) of this section).

(1) [Reserved]

(m) Examples:

(1) A declaration of 1½ pounds weight shall be expressed as “Net Wt. 24 oz (1 lb 8 oz),” “Net Wt. 24 oz (1½ lb),” or “Net Wt. 24 oz (1.5 lb)”.

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as “Net Wt. 12 oz”.

(3) A declaration of 1 quart liquid measure shall be expressed as “Net 32 fl oz (1 qt)”.

(4) A declaration of 1¾ quarts liquid measure shall be expressed as “Net contents 56 fluid ounces (1 quart 1½ pints)” or as “Net 56 fluid oz (1 qt 1 pt 8 oz)”, but not in terms of quart and ounce such as “Net 56 fluid oz (1 quart 24 ounces)”.

(5) On a random package, declaration of three-fourths pound avoirdupois may be expressed as “Net Wt. .75 lb”.

(6) A declaration of 2½ gallons liquid measure shall be expressed as “Net contents 2½ gallons,” “Net contents 2.5 gallons,” or “Net contents 2 gallons 2 quarts” and not as “2 gallons 4 pints”.

(n) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

weight wt	pint pt
ounce oz	quart qt
pound lb	fluid fl
gallon gal	

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents; *Provided*, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the food contained in the package; for example, “jumbo quart” and “full gallon”. Dual or combination declarations of net quantity of contents as provided for in paragraphs (a), (c), and (j) of this section (for example, a combination of net weight plus numerical count, net contents plus dilution directions of a concentrate, etc.) are not regarded as supplemental net quantity statements and may be located on the principal display panel.

(p) A separate statement of the net quantity of contents in terms of the

metric system is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(r) The declaration of net quantity of contents on pickles and pickle products, including relishes but excluding one or two whole pickles in clear plastic bags which may be declared by count, shall be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof.

(s) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (j)(1) of this section. A multiunit retail package may thus be properly labeled: “6-16 oz bottles—(96 fl oz)” or “3-16 oz cans—(net wt. 48 oz)”. For the purposes of this section, “multiunit retail package” means a package containing two or more individually packaged units of the identical commodity and in the same quantity, intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units or prevent examination of the labeling on each of the individual units are not

subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (f) and (i) of this section. The provisions of this section do not apply to that butter or margarine covered by the exemptions in § 1.24(a) (10) and (11) of this chapter.

(t) Where the declaration of net quantity of contents is in terms of net weight and/or drained weight or volume and does not accurately reflect the actual quantity of the contents or the product falls below the applicable standard of fill of container because of equipment malfunction or otherwise unintentional product variation, and the label conforms in all other respects to the requirements of this chapter (except the requirement that food falling below the applicable standard of fill of container shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter), the mislabeled food product, including any food product that fails to bear the general statement of substandard fill specified in § 130.14(b) of this chapter, may be sold by the manufacturer or processor directly to institutions operated by Federal, State or local governments (schools, prisons, hospitals, etc.): *Provided*, That:

(1) The purchaser shall sign a statement at the time of sale stating that he is aware that the product is mislabeled to include acknowledgment of the nature and extent of the mislabeling, (e.g., "Actual net weight may be as low as ___% below labeled quantity") and that any subsequent distribution by him of said product except for his own institutional use is unlawful. This statement shall be kept on file at the principal place of business of the manufacturer or processor for 2 years subsequent to the date of shipment of the product and shall be available to the Food and Drug Administration upon request.

(2) The product shall be labeled on the outside of its shipping container with the statement(s):

(i) When the variation concerns net weight and/or drained weight or volume, "Product Mislabeled. Actual net weight (drained weight or volume where appropriate) may be as low as ___% below labeled quantity. This Prod-

uct Not for Retail Distribution", the blank to be filled in with the maximum percentage variance between the labeled and actual weight or volume of contents of the individual packages in the shipping container, and

(ii) When the variation is in regard to a fill of container standard, "Product Mislabeled. Actual fill may be as low as ___% below standard of fill. This Product Not for Retail Distribution".

(3) The statements required by paragraphs (t)(2) (i) and (ii) of this section, which may be consolidated where appropriate, shall appear prominently and conspicuously as compared to other printed matter on the shipping container and in boldface print or type on a clear, contrasting background in order to render them likely to be read and understood by the purchaser under ordinary conditions of purchase.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

(a) The food industry is encouraged to experiment voluntarily, under controlled conditions and in collaboration with the Food and Drug Administration, with and other formats for presenting nutrition and other related food labeling information that is consistent with the current quantitative system in §§ 101.9 and 105.66 of this chapter.

(b) Any firm that intends to undertake a labeling experiment that requires exemptions from certain requirements of §§ 101.9 and 105.66 of this chapter should submit a written proposal containing a thorough discussion of each of the following information items that apply to the particular experiment:

(1) A description of the labeling format to be tested;

(2) A statement of the criteria to be used in the experiment for assigning foods to categories, e.g., nutrient or other values defining "low" and "reduced";

(3) A draft of the material to be used in the store, e.g., shelf tags, booklets, posters, etc.;

(4) The dates on which the experiment will begin and end and on which

a written report of analysis of the experimental data will be submitted to FDA, together with a commitment not to continue the experiment beyond the proposed ending date without FDA approval;

(5) The geographic area or areas in which the experiment is to be conducted;

(6) The mechanism to measure the effectiveness of the experiment;

(7) The method for conveying to consumers the required nutrition and other labeling information that is exempted from the label during the experiment;

(8) The method that will be or has been used to determine the actual nutritional characteristics of foods for which a claim is made; and

(9) A statement of the sections of the regulations for which an exemption is sought.

(c) The written proposal should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The proposal should be clearly identified as a request for a temporary exemption for purposes of conducting authorized food labeling experiments and submitted as a citizen petition under §10.30 of this chapter.

(d) Approval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product.

(e) Reporting requirements contained in §101.108(b) have been approved by this Office of Management and Budget and assigned number 0910-0151.

[48 FR 15240, Apr. 8, 1983, as amended at 59 FR 14364, Mar. 28, 1994; 62 FR 15343, Mar. 31, 1997]

APPENDIX A TO PART 101—MONIER-WILLIAMS PROCEDURE (WITH MODIFICATIONS) FOR SULFITES IN FOOD, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION (NOVEMBER 1985)

The AOAC official method for sulfites (*Official Methods of Analysis*, 14th Edition, 20.123-20.125, AOAC INTERNATIONAL) has

been modified, in FDA laboratories, to facilitate the determination of sulfites at or near 10 ppm in food. Method instructions, including modifications, are described below.

Apparatus—The apparatus shown diagrammatically (Figure 1) is designed to accomplish the selective transfer of sulfur dioxide from the sample in boiling aqueous hydrochloric acid to a solution of 3% hydrogen peroxide. This apparatus is easier to assemble than the official apparatus and the back pressure inside the apparatus is limited to the unavoidable pressure due to the height of the 3% H₂O₂ solution above the tip of the bubbler (F). Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

The apparatus should be assembled as shown in Fig. 1 with a thin film of stopcock grease on the sealing surfaces of all the joints except the joint between the separatory funnel and the flask. Each joint should be clamped together to ensure a complete seal throughout the analysis. The separatory funnel, B, should have a capacity of 100 ml or greater. An inlet adapter, A, with a hose connector (Kontes K-183000 or equivalent) is required to provide a means of applying a head of pressure above the solution. (A pressure equalizing dropping funnel is not recommended because condensate, perhaps with sulfur dioxide, is deposited in the funnel and the side arm.) The round bottom flask, C, is a 1000 ml flask with three 24/40 tapered joints. The gas inlet tube, D, (Kontes K-179000 or equivalent) should be of sufficient length to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, E, (Kontes K-431000-2430 or equivalent) has a jacket length of 300 mm. The bubbler, F, was fabricated from glass according to the dimensions given in Fig. 2. The 3% hydrogen peroxide solution can be contained in a vessel, G, with an i.d. of ca. 2.5 cm and a depth of 18 cm.

Buret—A 10 ml buret (Fisher Cat. No. 03-848-2A or equivalent) with overflow tube and hose connections for an Ascarite tube or equivalent air scrubbing apparatus. This will permit the maintenance of a carbon dioxide-free atmosphere over the standardized 0.01N sodium hydroxide.

Chilled Water Circulator—The condensor must be chilled with a coolant, such as 20% methanol-water, maintained at 5 °C. A circulating pump equivalent to the Neslab Coolflow 33 is suitable.

Reagents

(a) *Aqueous hydrochloric acid, 4N*.—For each analysis prepare 90 ml of hydrochloric acid by adding 30 ml of concentrated hydrochloric acid (12N) to 60 ml of distilled water.

(b) *Methyl red indicator*.—Dissolve 250 mg of methyl red in 100 ml ethanol.

(c) *Hydrogen peroxide solution, 3%*.—Dilute ACS reagent grade 30% hydrogen peroxide to